



VIA HAND DELIVERY DECEMBER 10, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
He et al.

Docket No.: PF150D2

Application No.: 10/021,002

Group Art Unit: 1642

Filed: December 19, 2001

Examiner: Not Yet Assigned

For: Human Prostatic Specific Reductase

RESPONSE TO INFORMAL NOTICE UNDER 42 U.S.C. § 2182

ATTN: LICENSING AND REVIEW SECTION
Commissioner for Patents
Washington, D.C. 20231

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JAN - 7 2003
LICENSING & REVIEW

RECEIVED
DEC 18 2002
GROUP 3600

Sir:

In response to the Informal Notice mailed on May 20, 2002, Applicants respectfully assert that 42 U.S.C. § 2182 is not applicable to the above-captioned application, and thus no statement should be required.

However, assuming *arguendo* that the Informal Notice is proper, Applicants submit herewith the statement required by 42 U.S.C. § 2182, executed by the Attorney of Record for the above-captioned application. Accordingly, the Informal Notice and 42 U.S.C. § 2182 have been fully complied with.

No fee is believed due in connection with this submission. However, should the Patent Office determine otherwise, please charge the required fee to Deposit Account No. 08-3425.

Dated: December 10, 2002

Respectfully submitted,

By Lin J. Hymel
Lin J. Hymel

Registration No.: 45,414
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 251-6015
Attorneys for Applicant

KKH/LJH/FR/ba



VIA HAND DELIVERY DECEMBER 10, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
He et al.

Docket No.: PF150D2

Application No.: 10/021,002

Group Art Unit: 1642

Filed: December 19, 2001

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LICENSING & REGISTRATION

Examiner: Not Yet Assigned

For: Human Prostatic Specific Reductase

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DEC 18 2002

GROUP 3600

DECLARATION UNDER 42 U.S.C. § 2182

1. I, Lin J. Hymel, Reg. No. 45,414, Attorney for Applicants, Customer Number 22195, hereby declare and state, on behalf of the inventors of record, as follows:

2. The inventors of record made and conceived the invention described and claimed in U.S. Application No. 10/012,002, filed on December 19, 2001.

3. The inventors of record made and conceived the above invention while employed by Human Genome Sciences, Inc. The above invention is related to the work the inventors of record were employed to perform and was made within the scope of their employment duties. To the best of my knowledge, the above invention was made during working hours and with the use of facilities, equipment, materials, funds, information, and services of Human Genome Sciences, Inc.

4. To the best of my knowledge, the above invention was not made or conceived in the course of, or in connection with, or under the terms of any contract, subcontract, or arrangement entered into with or for the benefit of the United States Atomic Energy Commission or its successors Energy Research and Development Administration or the Department of Energy.

5. I declare further that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: December 10, 2002

Respectfully submitted,

By Lin J. Hymel
Lin J. Hymel

Registration No.: 45,414
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 251-6015
Attorneys for Applicant

KKH/LJH/FR/ba

#7

DEC 10 2002

PTO/SB/17 (10-02)

Approved for use through 10/31/2002. OMB 0651-0032

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0.00

Complete if Known

Application Number	10/021,002-Conf. #9797
Filing Date	December 19, 2001
First Named Inventor	Wei-Wu He
Examiner Name	Not Yet Assigned
Group Art Unit	1642
Attorney Docket No.	PF150D2

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account

Deposit Account Number

08-3425

Deposit Account Name

Human Genome Sciences, Inc.

The Commissioner is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	740	2001	370	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	510	2003	255	Plant filing fee	
1004	740	2004	370	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	x	=
Multiple Dependent	-3** =	x	=

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee (\$)	Small Entity Fee Code	Small Entity Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	400	2252	200	Extension for reply within second month	
1253	920	2253	460	Extension for reply within third month	
1254	1,440	2254	720	Extension for reply within fourth month	
1255	1,960	2255	980	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,280	2453	640	Petition to revive - unintentional	
1501	1,280	2501	640	Utility issue fee (or reissue)	
1502	460	2502	230	Design issue fee	
1503	620	2503	310	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	740	2809	370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	740	2810	370	For each additional invention to be examined (37CFR 1.129(b))	
1801	740	2801	370	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0.00

SUBMITTED BY

Name (Print/Type) Lin J. Hymel

Registration No. (Attorney/Agent)

45,414

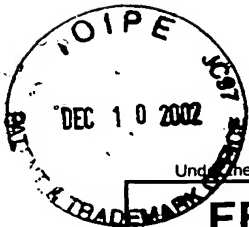
Complete (if applicable)

Telephone (301) 251-6015

Signature

Date

December 10, 2002



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
Approved for use through 10/31/2002. OMB 0651-0032
PTO/SB/17 (10-02)

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Complete if Known

Application Number	10/021,002-Conf. #9797
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First Named Inventor	Wei-Wu He
Examiner Name	Not Yet Assigned
Group Art Unit	1642
Attorney Docket No.	PF150D2

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

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Deposit Account Number

08-3425

Deposit Account Name

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SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

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1801	740	2801	370	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0.00

SUBMITTED BY

Name (Print/Type) Lin J. Hymel

Signature

Registration No. (Attorney/Agent)

45,414

Complete (if applicable)

Telephone (301) 251-6015

Date

December 10, 2002

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GROUP 3600



1642

VIA HAND DELIVERY DECEMBER 10, 2002

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
He, et al.

Docket No.: PF150D2

RECEIVED

DEC 12 2002

Application No.: 10/021,002

Group Art Unit: 1642 TECH CENTER 1600/290

Filed: December 9, 2001

Examiner: Unassigned

For: Human Prostatic Specific Reductase

**REQUEST FOR CORRECTED PUBLICATION UNDER 37 C.F.R. § 1.221(b)
DUE TO MATERIAL OFFICE MISTAKE**

Box PGPUB
Commissioner for Patents
Washington, D.C. 20231

RECEIVED

DEC 18 2002

GROUP 3600

Sir:

Applicants respectfully request a corrected publication of the above-listed application pursuant to 37 C.F.R. § 1.221(b) due to a material mistake made by the U.S. Patent and Trademark Office. In particular, the publication (US 2002/0150578 A1) improperly lists the filing date and the Application Serial Number of the International Application to which the instant application claims benefit under 35 U.S.C. § 119(e).

The above mistake is apparent from Office records, as the Application Data Sheet and the first paragraph of the present application each contain the correct serial number and date of priority application. A copy of the first page of the published priority application is attached as Exhibit A. Moreover, the above mistake is material, because the improper priority claim affects the identification of the correct PCT priority application and use of the published application as prior art under 35 U.S.C. § 102(e). In particular, without the correct date for the priority application being listed, an examiner or member of the public would be unable to determine the correct effective date of the publication as a reference for at least some of the subject matter

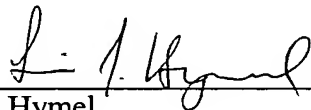
disclosed therein. In order to make such a determination from the present publication, an examiner or member of the public would first be forced to obtain the correct priority information from the Office, thus undermining the use of the publication (and published applications in general) for § 102(e) purposes.

Accordingly, Applicants respectfully request that a corrected publication of the above-listed application be made pursuant to 37 C.F.R. § 1.221(b).

No fee is believed due for this submission. In the event that a fee is required in connection with this submission, please charge the required fee to Deposit Account No. 08-3425.

Dated: December 10, 2002

Respectfully submitted,

By 
Lin J. Hymel

Registration No.: 45,414
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 251-6015
Attorneys for Applicant

KKH/LJH/FR/ba

3012/12-

3600
#9

**HUMAN GENOME SCIENCES
LEGAL DEPARTMENT**

9410 Key West Avenue
Rockville, MD 20850

Phone: 301-309-8504

Fax: 301-309-8439

FAX COVER SHEET

Date: December 10, 2002

Total pages: 8

To: Group 1600 Customer Service Center
U.S. Patent and Trademark Office

Fax 703-746-9195

From: Brenda Allen (301) 340-3459
for Lin J. Hymel (Reg. No. 45,414)

Re: Application Serial No. 10/021,002 (Atty. Docket No. PF150D2)

TRANSMITTING:

1. Request for Corrected Filing Receipt (2 pages);
2. Copy of Filing Receipt with correction noted thereon (2 pages); and
3. Copy of page 1 of Specification and page 3 of Application Data Sheet filed with instant application, along with a copy of the PTO date-stamped postcard evidencing receipt of same (3 pages).

If you experience any difficulty receiving this transmission,
please contact Brenda Allen at 301-340-3459

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VIA FACSIMILE TRANSMISSION TO
GROUP 1600 CUSTOMER SERVICE
(703/746-9195) DECEMBER 10, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
He et al.

Docket No.: PF150D2

Application No.: 10/021,002

Group Art Unit: 1642

Filed: December 19, 2001

Examiner: Not Yet Assigned

For: Human Prostatic Specific Reductase

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicants hereby request that a corrected Filing Receipt be issued and sent to the undersigned representative. Specifically, the following correction is requested:

1. Under the heading Domestic Priority as claimed by applicant, please change
"WHICH IS A CIP OF PCT/US95/08127 06/29/1995*" to read
--WHICH IS A CIP OF PCT/US95/01827 01/20/1995--.

In support of the above request, Applicants submit herewith a copy of first page of the Specification and a copy of page 3 of the Application Data Sheet filed in the instant application, along with a copy of the PTO date-stamped postcard evidencing receipt of these items with the initial application papers. A copy of the Filing Receipt with the correction noted thereon is also attached.

Applicants additionally request that all pertinent U.S. Patent and Trademark Office records relating to the subject application be changed to reflect this correction.

Applicants believe no fee is due with this request because the error was generated by the Patent and Trademark Office. However, if a fee is due, please charge our Deposit Account No. 08-3425.

Dated: 10 December 2002

Respectfully submitted,

By Lin J. Hymel
Lin J. Hymel

Registration No.: 45,414
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 251-6015
Attorneys for Applicant

KKH/LJH/FR/ba

HUMAN PROSTATIC SPECIFIC REDUCTASE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of U.S. Application No. 09/123,386, filed July 27, 1998, allowed, which is a divisional of U.S. Application No. 08/464,400 filed June 5, 1995, now U.S. Patent No. 5,786,204 which is a continuation-in-part of International Application No. PCT/US95/01827 filed January 20, 1995, which was published by the International Bureau as International Publication No. WO96/22360 on July 25, 1996 in English, each of which is hereby incorporated by reference in its entirety.

INTRODUCTION

[0002] This invention relates to newly identified polynucleotides, polypeptides encoded by such polynucleotides, and the use of such polynucleotides and polypeptides as part of a diagnostic assay for detecting the presence of prostate cancer and prostate cancer metastases. The polynucleotides and polypeptides of the present invention are human prostatic specific reductase, and are sometimes hereinafter referred to as "PSR".

BACKGROUND OF THE INVENTION

[0003] Carcinoma of the prostate has long been regarded as an unpredictable disorder which makes sound therapeutic decisions in evaluating the results of different types of treatment very difficult. Prostate cancer is unique among the potentially lethal human malignancies in that there is a wide discrepancy between the high prevalence of histologic changes recognizable as cancer and the much lower prevalence of clinical disease.

[0004] The concept that adenocarcinoma of the prostate exists in a latent and a clinical form is supported by epidemiologic, pathologic and clinical evidence. Although these divergent manifestations of prostate cancer have come in architectural and cytologic features, they can be distinguished from each other to some degree by differences in certain pathologic features, such as the volume, grade, and invasiveness of the lesion.

[0005] Prostate cancer has become the most common cancer among American men, and only lung cancer is responsible for more cancer deaths (Boring, C.C., Cancer Statistics, 41:19-36 (1991)). The age specific mortality rate has slowly increased over the past 50 years and in black American men is nearly double the rate found in white men

Applicant Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Full Capacity
Given Name:: Craig
Middle Name:: A.
Family Name:: Rosen
City of Residence:: Laytonsville
State or Province of Residence:: MD
Country of Residence:: US
Street of mailing address:: 22400 Rolling Hill Lane
City of mailing address:: Laytonsville
State or Province of mailing address:: MD
Country of mailing address:: US
Postal or Zip Code of mailing address:: 20882

Correspondence Information


Correspondence Customer Number:: 22195

Representative Information


Representative Customer Number:: 22195

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	Division of	09/123,386	07/27/98
09/123,386	Division of	08/464,400	06/05/95
08/464,400	Continuation-in-part of	PCT/US95/01827	01/20/95



RETURN RECEIPT CARD
(MPEP § 503)

OIPE:	Please Date Stamp In The Box Below And Return To Addressee
	

Application of: He et al.

Attorney Docket No.: PF150D2

Application Serial No.: Unassigned

Art Unit: Unassigned

Filed: Herewith

Examiner: Unassigned

Title: Human Prostatic Specific Reductase

**The following documents were filed by Human Genome Sciences, Inc.
via hand delivery on December 19, 2001:**

1. Return Receipt Card;
2. Serial Number Postcard;
3. Fee Transmittal with appropriate fee(s) (in duplicate);
4. Utility Application Transmittal;
5. Application Data Sheet (4 pgs.);
6. Specification: 31 pgs. Description; 4 pgs. [40] Claims; 1 pg. Abstract;
7. Sequence Listing in written (on paper) (4 pgs.) and computer readable forms;
8. Statement Under 37 C.F.R. 1.821(f);
9. Figures 1A-1B and 2A-2D (6 sheets);
10. Information Disclosure Statement with Form PTO/SB/08 and copy of reference AR;
11. Copy of executed Declaration from prior Application No. 08/464,400; and
12. Copy of Assignment papers from prior Application No. 08/464,400.

JKE/CCB/ba